

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Radunsky, et al.
Application No.: 10/796,882 Group No.: 1723
Filed: Mar. 8, 2004 Examiner: Drodge, Joseph W.
For: Method and System for Colloid Exchange Therapy

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;*
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or*
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).*

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;*
- (2) each attorney or agent who prepares or prosecutes the application; and*
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).*

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

(Information Disclosure Statement--page 1 of 7)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Radunsky, et al. Attorney Docket: 3154/103
 Serial No: 10/796,882 Art Group Unit: 1723
 Date Filed: Mar. 8, 2004 Examiner Name: Drodge, Joseph W.
 Invention: Method and System for Colloid Exchange Therapy

LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AA	6,620,382	Sep. 16, 2003	Lentz	422/44
	AB	6,231,536	May 15, 2001	Lentz	604/5.04

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	AC	Falkenhagen, et al.	"Fractionated Plasma Separation and Adsorption System: A Novel System for Blood Purification to Remove Albumin Bound Substances", <u>Artificial Organs</u> , Vol. 23(1), pp. 81-86, (1999)
	AD	Rifai, et al.	"Prometheus® - a New Extracorporeal System for the Treatment of Liver Failure", <u>Journal of Hepatology</u> , Vol. 39, pp. 984-990, (2003)
	AE	Evenepoel, et al.	"Detoxifying Capacity and Kinetics of Prometheus® - A New Extracorporeal System for the Treatment of Liver Failure, <u>Blood Purification</u> , Vol. 23, pp. 349-358, (2005)
	AF		"The Prometheus® System", <u>http://www.biotech-systems.at/en/Prometheus.html</u> , Biotec Systems Krems GmbH
	AG	Vienken and Christmann	"How Can Liver Toxins be Removed? Filtration and Adsorption With the Prometheus System," <u>Therapeutic Apheresis and Dialysis</u> , Vol 10(2), pp. 125-131, (2006)

/Joseph Drodge/

03/31/2008

(Information Disclosure Statement--page 4 of 7)

Examiner Signature: /Joseph Drodge/

Date Considered: 03/31/2008

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application.
(37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

**/Robert A. Hess, #57,411/
SIGNATURE OF PRACTITIONER**

Robert A. Hess
(type or print name of practitioner)

125 Summer Street, 11th Floor
P.O. Address

Boston, MA 02110-1618

Reg. No.: 57,411

Tel. No.: (617) 443-9292

Customer No.: 002101

03154/00103 815826.1